

Message Text

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ORIGIN HEW-06

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DRAFTED BY DHEW/FDA: LRSHELTON:CCK
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FM SECSTATE WASHDC

TO AMEMBASSY NICOSIA PRIORITY

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E.O. 11652: N/A TAGS: TBIO, BDIS,CY, US

SUBJECT: CYPRUS COMPLAINT OF SUB-STANDARD DRUGS

REF: 75 NICOSIA 0323, 75 STATE 263588, 75 STATE
234830, 76 STATE 63126

1. FDA WOULD APPRECIATE POST FORWARDING FOLLOWING MESSAGE
TO DR. EFTYCHIOS KKOLOS, REGISTRAR OF PHARMACY AND POISONS
BOARD, MINISTRY OF HEALTH, BYRON AVENUE, NICOSIA, CITING
HIS REFERENCE M.H. 464/70/111.

2. THE ALLIED BIOCHEMICAL INVESTIGATION HAS BEEN FORWARDED
TO FDA HEADQUARTERS.

3. IT IS A MOST SERIOUS VIOLATION OF THE UNITED STATES
FEDERAL FOOD, DRUG AND COSMETIC ACT TO EXPORT FROM THE U.S.A.
ANY DRUG THAT FAILS TO MEET ALL THE REQUIREMENTS OF THE ACT
UNLESS IT ACCORDS TO THE SPECIFICATIONS OF THE FOREIGN PUR-
CHASER AND IS NOT IN CONFLICT WITH THE LAWS OF THE COUNTRY
TO WHICH IT IS INTENDED FOR EXPORT. WE INTEND TO PURSUE
THIS MATTER VIGOROUSLY.

4. AFTER REVIEWING THE CASE IT APPEARED ADVISABLE TO HAVE
AN INVESTIGATOR FROM THE FOOD AND DRUG ADMINISTRATION VISIT
CYPRUS, AND WITH YOUR APPROVAL COLLECT ADDITIONAL SAMPLES.

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IF THIS WERE NOT DONE AND LEGAL ACTION APPEARS INDICATED,

AT TRIAL WE WOULD NEED THE MINISTRY OF HEALTH AGENTS WHO

COLLECTED THE SAMPLES AND THE ANALYSTS TO TESTIFY IN PERSON, AND BE SUBJECT TO CROSSEXAMINATION BY THE DEFENSE. THIS EXPENSE AND INCONVENIENCE CAN BE EASILY AVOIDED SINCE AN FDA INVESTIGATOR HAS ALREADY BEEN SCHEDULED TO BE IN THE MEDITERRANEAN AREA.

5. MR. NICOS CHRISTODOULIDES WAS TELEPHONED ON AUGUST 5, 1976 TO REQUEST HIS COOPERATION: HE ADVISED ME HE WOULD BE MOST HAPPY TO RECEIVE INVESTIGATOR CHARLES WAYNE ON OR ABOUT OCTOBER 11, 1976. WHEN THE INVESTIGATOR VISITS MR. CHRISTODOULIDES HE WOULD APPRECIATE HAVING A MINISTRY OF HEALTH AGENT PRESENT SINCE WE UNDERSTAND THE DRUGS ARE UNDER YOUR SEAL.

6. WE INTEND TO KEEP BOTH YOU AND MR. CHRISTODOULIDES ADVISED ON WHATEVER DECISIONS ARE MADE. IF YOU ANTICIPATE ANY PROBLEMS OR DESIRE INFORMATION, PLEASE FEEL FREE TO CONTACT MR. KENTER AT THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE, PUBLIC HEALTH SERVICE, FOOD AND DRUG ADMINISTRATION, 5600 FISHERS LANE, ROCKVILLE, MARYLAND 20852, TELEPHONE 301-443-1940. ROBINSON

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